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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,288	03/10/2004	Marlene M. Darfler	26204-002US	9373

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EXAMINER
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SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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02/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/796,288	<b>Applicant(s)</b> DARFLER ET AL.	
	<b>Examiner</b> KAILASH C. SRIVASTAVA	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 18-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/31/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

1. Request for continued examination (i.e., R.C.E.) under 37 C.F.R. §1.114, including the fee set forth in 37 C.F.R. §1.17(e), was filed in this application on 31 October 2007 after a Final action mailed on 10 August 2007. Since this application is eligible for continued examination under 37 C.F.R. §1.114, and the fee set forth in 37 C.F.R. §1.17(e) has been timely paid, the finality of the previous Office action mailed 10 August 2007 has been withdrawn pursuant to 37 C.F.R. §1.114. Applicants' submission filed 31 October 2007 has been entered. Accordingly an R.C.E. has been established and the action on R.C.E. follows.
2. Response filed 31 October 2007 to the Office Action mailed 10 August 2007 are acknowledged and entered.
3. Declaration of Ms. Marlene Darfler under 37 C.F.R. §1.132 filed 31 October 2007 is acknowledged, entered and considered. The response to facts presented in said Declaration are discussed below under Claim Rejections.

## **Claims Status**

4. Claims 1-39 are pending.
5. Claims 18 -39 remain withdrawn.
6. Claims 1-17 are under consideration and are examined on merits.

## **NON-RESPONSIVE RESPONSE CONSIDERED**

7. Please note, the timely submission filed on 31 October 2007 is not fully responsive to the prior Office action mailed 10 August 2007; because in said Final Action, a requirement was placed to cancel claims 18-39 (See Page 2, Lines 6-7 of the Office Action mailed 10 August 2007) previously withdrawn as being non-elected claims in response to an election restriction requirement (See Response filed 11/114/2006). Since the submission appears to be a *bona fide* attempt to provide a complete reply to the prior Office action, in the interest of advancing the prosecution of the instant application following action on the R.C. E. identified *supra* follows.
8. In response to this Office Action, please cancel withdrawn claims 18-29 drawn to a non-elected invention without traverse in the response filed 14 November 2006.

***Claim Rejections - 35 U.S.C. § 102 (b)***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

10. Claims 1-17 are rejected under 35 U.S.C. §102(b) as being anticipated by Wang et al (US 5,672,696, issued 30 Sept 1997, from IDS dated 29 May 2007).

11. Claims 1-4 and 7-17 stand rejected under 35 U.S.C. §102(b) as being anticipated by Banerjee et al (Biotechniques, 1995, from Applicants' IDS).

Claims recite a method to prepare a biomolecule lysate through the steps of:

- (a) deparafinizing a formalin fixed /paraffin embedded tissue/cells comprising a histopathologically processed biological sample;
- (b) heating said sample and a reaction buffer for a given time at a given temperature to reverse /release proein crosslinking in said biological sample; and
- (c) subsequently, treating said composition with a protease enzyme to disrupt the tissue and cellular structure of said biological sample;
- (d) obtaining said biomolecule lyasate in a soluble liquid form, wherein contents of said biomolecule lysate is representative of the total protein content of said histopathologically processed biological sample; and
- (e) said biomolecule lysate is suitable for protein expression analysis.

Additional claims depending from the independent claim are drawn to homogeneous population of tissue or cells in said biological sample, manual mixing to mechanically disrupt said sample, the heating temperature within the range of 80°C -100°C for 10 mins to 4 hours, proteolytic enzyme treatment for 30 mins to 24 hours at 37 °C-65 °C, buffer is Tris at a pH of 6.0-9.0, additionally comprising a detergent, subsequent fractionation of biomolecule lysate in to distinct and separate biomolecules for biochemical assay.

12. Arguments presented in the response filed 31 October 2007, especially in consideration of Ms. Darfler's Declaration are addressed below.

In response to rejections made in the Office action mailed 10 August 2007 under 35 U.S.C. § 102(b) to Claims 1 -17 as anticipatory by Wang et al., and Claims 1-4 and 7-17 as being anticipated by Banerjee et al., respectively; applicants argue that said Claims are not anticipated by each of the cited prior responses. Responding to the anticipatory rejections made by Examiner-cited each of the prior art references, applicants further argue, that Ms. Darfler conducted side by side experiments to prepare biomolecule lysate "consistent with the method of Claim 1" and according to the protocols discussed in each of Wang et al. and Banerjee et al's references (See Remarks filed 31 October 2007, Page . In Ms. Darfler's hands, the biomolecule lysate prepared according to the instantly claimed method of Claim 1 yielded a biomolecule lysate having properties dissimilar than those prepared according to either Wang et al's protocol, or Banerjee et al's protocol as illustrated in the Table below. Said Table has been integrated on the basis of information presented in Remarks filed 31 October 2007.

Parameter	Method Consistent with instant Claim 1	Wang et al's Protocol	Banerjee et al's Protocol
Appearance of biomolecule lysate in a tube	Visible soluble liquid	One insoluble, one soluble and one soluble after DNA precipitation	Lysate is in a visibly soluble form and an insoluble form
Identified number of proteins and peptides from soluble liquids by MS as a representation of overall protein expression	1,251 different unique proteins	Visible Liquid 107 Resuspended DNA Fraction 12	15
Number of regions identified from GO analysis	124	Visible liquid 30 DNA Fraction 8	8
Identified Number of Proteins Involved in Normal Liver Function	677 or 54%	13 or 10.9	2 or 25%
Number of Liver Function enzymes assayed for in blood that were identified in Lysate	4	None	None
Ms. Darfler Conclusion	Lysate represents starting material	Lysate does not represents starting material	Lysate does not represents starting material

Applicants arguments presented on the basis of Ms. Darfler's declaration, however does not elaborate if Wang et al's or Banerjee et al's protocol differs in method steps from the instantly claimed method claim steps as those named in item 11a-11e and in the dependent claims. Applicants' arguments are rather regarding the differences in the number of soluble and insoluble layers, number of identifiable proteins, number of regions obtained from GO analysis and identified number of liver function proteins and number of liver function diagnostic proteins identified in the blood samples, items that are not the instantly claimed subject matter. Accordingly, applicants' arguments are drawn to non-claimed subject matter, because contrary to information presented in Ms. Darfler's Declaration cited *supra*, the claimed invention is drawn to a method to prepare a biomolecule lysate from the paraffin embedded histopathologically processed biological sample, where in said lysate comprises soluble protein and comprises proteins representing the original biological sample. In view of data presented in Ms. Darfler's declaration filed 31 October 2007, applicants have, however, not pointed out, how the information presented in Ms. Darfler's declaration renders the instantly claimed method or method steps not being anticipated by the teachings from Wang et al. and Banerjee et al. respectively. Therefore, the instantly claimed invention as claimed in currently presented Claims is anticipated by each of Wang et al. and Banerjee et al.

Applicants' arguments filed 31 October 2007 regarding the rejections to Claims 1-17 as anticipated by Wang et al., and Claims 1-4 and 7-17 as being anticipated by Banerjee et al., respectively in the Office Action dated 10 August 2007 have been fully and carefully considered but are not persuasive for the reasons of record at page 2, Line 13 to Page 4, Line 9 in the Office Action dated 10 August 2007 and those pointed out *supra*. This is because each of the references teaches a method comprising same components and steps as are recited in instantly claimed claims 1-17.

### Conclusion

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 C.F.R. §1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 C.F.R. §1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 C.F.R. §1.114. See M.P.E.P. §706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. For the aforementioned reasons, no Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

/Dr. Kailash C Srivastava/  
Examiner, Art Unit 1657

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1657

February 27, 2008